



April 22, 2020

Demetrios Kouzoukas
Principal Deputy Administrator & Director, Center for Medicare
Centers for Medicare & Medicaid Services
Mail Stop 301H
200 Independence Ave., SW
Washington, DC 20201

Re: Recommendations on Establishing Payment Amounts for COVID-19 Antibody Test Codes

Dear Mr. Kouzoukas:

On behalf of AdvaMedDx, we are writing to the Centers for Medicare & Medicaid Services (CMS) regarding recent CMS activity surrounding coding and reimbursement for COVID-19 diagnostic testing codes. We urge CMS to consider specific recommendations for establishing national payment amounts for new diagnostic test codes needed to support the nation's response to the COVID-19 public health emergency.

AdvaMedDx represents the world's leading diagnostics manufacturers by advocating for the value and power of medical diagnostic tests to promote wellness, improve patient outcomes, and advance public health in the United States and abroad. AdvaMedDx member companies produce innovative, safe and effective diagnostic tests that facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease and often reduce health care costs.

First, we commend CMS for its recent decision to increase the payment for certain clinical diagnostic laboratory tests (CDLTs) for detecting SARS-CoV-2 to diagnose the virus that causes COVID-19. We agree with CMS's rationale for increasing payments for those tests that use high throughput technologies to more accurately reflect the increased resources required for those tests; and we appreciate CMS's recognition of the complex laboratory ecosystem.

Second, in focused efforts to address the COVID-19 public health emergency, both CMS and the AMA-CPT Editorial Panel have taken unprecedented actions to establish, mid-year, new codes for laboratory tests paid under the clinical laboratory fee schedule (CLFS). While payment amounts for tests paid under the CLFS are typically assigned for the following year using the processes outlined in CMS's regulations at 42 CFR § 414.506 and 42 CFR § 414.508, CMS has deviated from that process to assign Medicare Administrative Contractor (MAC)-specific or national payment amounts for new codes U0001, U0002, U0003 and U0004 that are used to identify the SARS-CoV-2 virus that causes COVID-19.

AdvaMedDx believes it is equally important to establish national payment amounts for two new CPT codes used to describe COVID-19 antibody testing:

- 86769 Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])

- 86328 Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])

Antibody testing for SARS-CoV-2 will be critical to identifying people that may have acquired immunity for COVID-19 and will provide information on the extent of the disease's spread in the population that will be critical for targeting future public health initiatives.

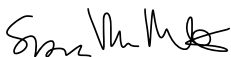
We understand that several groups and organizations, including the American Clinical Laboratory Association (ACLA), have submitted recommendations to CMS to establish national payment amounts for these new CPT codes by crosswalking payment from existing CPT code 86794 (Zika antibody test) and applying a multiplier to reflect additional resources required to perform the tests.

We are writing to support the ACLA recommendation to crosswalk CPT code 86769 (typically performed in a central lab) to 2.5x CPT code 86794. We agree with ACLA that this is an appropriate crosswalk, considering the resources required to perform the test and the unprecedented need to make testing more widely available in a very short timeframe.

We also understand that other groups have submitted a similar crosswalk recommendation (2.5x 86794) for CPT code 86328 (typically point of care). AdvamedDx does not oppose this crosswalk proposal.

AdvaMedDx supports efforts to ensure that reimbursement for SARS-CoV-2 antibody testing appropriately represents the unique and additional costs associated with critical diagnostic testing in this public health emergency. Thank you for considering these comments and please contact me or Chandra Branham at cbranham@advamed.org if you have questions or require additional information.

Sincerely,



Susan Van Meter
Executive Director, AdvaMedDx

cc: Ing-Jye Cheng, Acting Director, Hospital & Ambulatory Policy Group, CMS
Ryan Howe, Deputy Director, Hospital & Ambulatory Policy Group, CMS
Sarah Shirey-Losso, Director, Division of Ambulatory Services, CMS